Ramon Rossi Lopez - rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Mark S. O'Connor (011029) - mark.oconnor@gknet.com
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
602-530-8000

Co-Lead/Liaison Counsel for Plaintiffs

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' RESPONSE IN OPPOSITION TO MOTION TO EXCLUDE THE OPINIONS OF DAVID KESSLER, M.D.**

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Plaintiffs oppose Defendants C.R. Bard, Inc. and Bard Peripheral Vascular ("Bard") Motion to Exclude the Opinions of David Kessler, M.D. [ECF 7309.] Plaintiffs incorporate in this response their Omnibus Statement of Law and Generally-Applicable Arguments in Opposition to Bard's Motions to Exclude Plaintiffs' Experts under Rule 702 and *Daubert* [Doc. 7799], filed contemporaneously herewith. For the reasons set forth herein and in the Omnibus Memorandum, this Court should deny the Motion.

I. INTRODUCTION

Dr. Kessler, former commissioner of the Food and Drug Administration ("FDA") is indisputably qualified to provide opinions on regulatory issues as they relate to Bard's development and marketing of its IVC filters. There can also be no dispute that the field of medical device regulation is a complicated one, and that expert testimony will assist the fact-finder in understanding it; indeed, Bard has offered its own experts' opinions on regulatory issues. Dr. Kessler's conclusions are also reliable, as they are based on his painstaking and detailed review of voluminous record evidence.

In its motion and accompanying brief ("Mem."), Bard does not provide any legitimate basis to exclude Dr. Kessler's opinions. Ignoring numerous judicial decisions in which courts have admitted Dr. Kessler's testimony and rejected precisely the arguments that Bard makes here, Bard repeatedly complains about the length of Dr. Kessler's reports, as if his opinions are based *too* thoroughly on the evidence. Dr. Kessler's reports provide a clear and detailed factual basis for his opinions, as the rules require.

In addition to complaining that his reports are too long, Bard also complains that Dr. Kessler is, essentially, too qualified to offer opinions. Bard attempts to warn the Court that "[l]eft unchecked," Dr. Kessler "will trade on [his] experience to supplant the Court and personally instruct the jury about what law to apply." Mem. at 2. But as this Court and others have repeatedly observed, no witness is "left unchecked." Expert witness testimony should be and will be tested through the "traditional tools of the

adversary system," including "'[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof….'" *Wichansky v. Zowine*, No. CV-13-01208, 2016 WL 6818945, at *3 (D. Ariz. Mar. 22, 2016) (quoting *Daubert v. Merrill Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993)).

The same principles apply to Dr. Kessler. He is plainly qualified to offer the opinions set out in his reports, which concern complex regulatory issues and which will assist the jury in understanding the framework and processes within which Bard developed and marketed the filters at issue, as well as the standard of care applicable to Bard, and whether Bard failed to meet that standard.

II. DR. KESSLER'S QUALIFICATIONS

As his first report sets forth (*see* Rep. ¶¶ 1-6), Dr. Kessler was appointed in 1990 by President George H.W. Bush as FDA Commissioner, and continued to serve in that position under President Clinton until February 1997. He received a medical degree from Harvard Medical School in 1979 and a law degree from the University of Chicago Law School in 1978.

As FDA Commissioner, Dr. Kessler had ultimate responsibility for implementing and enforcing the United States Food, Drug, and Cosmetic Act ("FDCA"), and was responsible for overseeing five Centers within FDA, including the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research. Dr. Kessler is a senior advisor to a global private equity firm that owns pharmaceutical and biomedical companies, and serves on the boards of two pharmaceutical companies. In these capacities, Dr. Kessler advises corporations on the standards of care within the pharmaceutical industry under state and federal law.

Dr. Kessler has testified many times before the United States Congress on food, drug, and consumer protection issues under federal and state law. Over the last thirty-five years, he has published numerous articles in legal, medical, and scientific journals on the federal regulation of drugs and medical devices, as well as the complementary role of federal regulations and state common law.

Dr. Kessler has previously testified at numerous trials following denial of *Daubert* motions in federal and state courts, on matters similar to those at issue in this case, involving duties of care in the marketing and warning of risks of drugs and devices, and the applicability of federal and state law standards. *See, e.g., Wells v. Allergan, Inc.*, No. CIV-12-973-C, 2013 WL 7208221 (W.D. Okla. Feb. 4, 2013); *In re Actos (Pioglitazone) Prod. Liab. Litig.*, No. 12-CV-00064, 2014 WL 120973, at *14 (W.D. La. Jan. 10, 2014).[12] Dr. Kessler's opinions also have survived similar *Daubert* challenges following deposition testimony in other litigations. *See, e.g., In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 6302287, at *12 (S.D. Ill. Dec. 16, 2011); *In re Xarelto (Rivaroxaban) Prod. Liab. Litig.*, No. MDL 2592, 2017 WL 1352860, at *3 (E.D. La. Apr. 13, 2017). Dr. Kessler's published work in this field was cited by the U.S. Supreme Court with approval in *Wyeth v. Levine*, 555 U.S. 555 (2009), which held that federal regulations do not preempt the state law duty to warn.

III. SUMMARY OF DR. KESSLER'S OPINIONS

Dr. Kessler's reports are based on his careful review and citation to the factual record concerning Bard's inadequate warning of the risk of serious and life-threatening adverse events associated with its filters, as well as its failure to comply with applicable Federal regulations, withholding of critical data showing the filters' inadequacies, and promotion of the filters for improper off-label use, as summarized below.[3]

After setting out the regulatory framework that applies to the filters at issue, Dr. Kessler's first report explains that Bard had an obligation to ensure that the Recovery

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[1] Dr. Kessler has submitted three reports in this litigation, which were attached to Bard's motion as Exhibits A, B, and C. The first report ("Rep.") focused primarily on the Recovery and G2 devices; the second ("Supp. Rep.) on the Eclipse filter, and the third (Second Supp. Rep.") on preemption issues.

[2] *See also In re Neurontin Mktg. & Sales Practices Litig.*, No. 04-CV-10739-PBS, 2011 WL 3852254, at *48 n.2 (D. Mass. Aug. 31, 2011) (describing Dr. Kessler, after trial testimony in which no *Daubert* motion was filed against him, as "an expert on how the [FDA] works and how a pharmaceutical company interacts with the FDA.").

[3] Dr. Kessler's opinions are detailed in the concluding sections of each of his Reports.

filter was at least as safe and effective as the Simon Nitinol Filter (SNF), the device that Bard referenced as a "predicate" to gain clearance under section 510(k) of the FDCA. *See* Rep. ¶¶ 66-71. Reviewing Bard internal documents and submissions to the FDA, Dr. Kessler explains that Bard was aware, both before and after marketing, that the Recovery was, neither as safe nor as effective as the SNF. By 2004, shortly after the full-market launch of the product, Bard's analyses showed a statistically significantly increased reporting rate of death with Recovery compared to SNF, *and* that Recovery had statistically significantly weaker resistance to migration than SNF. These mutually reinforcing lines of evidence were never disclosed to doctors, patients, or the FDA. *See id.* ¶¶ 72-142, 248, 577.

Dr. Kessler's report describes the Recovery filter's failure to meet resistance standards in an internal engineering test report from March 2004. ¶¶ 154-55. Therefore, Dr. Kessler explains, the quality of the Recovery fell below that which it was represented to possess, meeting the definition of an "adulterated" product under the FDCA, and could not be legally marketed. *Id.* ¶ 156. In April 2004, Bard prematurely lifted a "QA [Quality Assurance] Hold" on the sale of the Recovery filter, despite evidence of increased risks the filter presented to patients and Bard's efforts to design a new filter to address those risks. *Id.* ¶¶ 158-63, 182-190; 564-67.

Even as Bard was aware of those risks, it did not remove the Recovery from the market. *See id.* ¶¶ 182-189. Dr. Kessler concludes that if Bard had removed the Recovery filter from the market in April/May 2004, as it should have, there would have been no legally marketed predicate for Bard to have claimed substantial equivalence for a new device. Thus, the G2 Filter, which had the Recovery as its predicate, could not have been legally marketed. *Id.* ¶¶ 190, 570. Dr. Kessler concludes that Bard should not have continued to sell the Recovery while it was aware of the filter's increased risks. *Id.* § V(D), ¶ 571. Further, having done safety analyses utilizing adverse event reporting rates in conjunction with preclinical testing to ensure the safety of its device (which Dr. Kessler carefully reviews), Bard had an obligation to share that information with

patients and physicians so that they could make proper and informed decisions concerning the use of the device. Bard should have shared that information with FDA, particularly in light of FDA's expression of concern (*see* ¶¶ 315-24) about the safety of the Recovery. *Id.* ¶ 577.

Dr. Kessler's report also reviews Bard's testing, development and marketing of, and adverse events data for, the G2 filter. He concludes that, as of November 27, 2006, the G2 filter, having failed Bard's internal migration resistance test, also fell below the quality it was represented to possess, and was thus "adulterated" under the FDCA. *Id.* ¶ 376, 583. Dr. Kessler concludes that the G2 filter "presented an unacceptable risk." *Id.* ¶ 510.

Dr. Kessler also reviews Bard's development of successive filters. He encapsulates this process as "a succession of design changes, followed by safety problems, followed by subsequent design changes." *Id.* ¶ 461. This iterative process put patients at risk because Bard failed to ensure that the filters it placed on the market did not raise new safety questions. *Id.* ¶ 464. Dr. Kessler concludes that "Bard was "beta testing" its IVC filters in patients. *Id.* ¶ 465.

Dr. Kessler also provides a detailed review of Bard's representations about its filters in its sales and marketing materials, "Dear Doctor" letters, and internal statements/directives to its sales force, including representations that Recovery and G2 filters were equivalent to or more migration-resistant than the SNF, "older filters" and competitor filters, that migration of the filter was a known complication of all vena cava filters, or a so-called "class effect," and that the Recovery and G2 filters were a marked improvement over currently available devices and were the latest advancement in filter technology. *Id.* § VII-IX. Dr. Kessler concludes, after an exhaustive review of the evidence, that these were misleading statements. *Id.*; ¶¶ 591-92.

Based on his review, Dr. Kessler concludes, "If Bard wanted to sell a filter as a retrievable filter for permanent use, it should have conducted clinical studies to evaluate the safety and efficacy of these devices as permanent devices. Moreover, if Bard wanted

to sell a permanent device with a retrievable option that had different technology from prior filters, it should have conducted clinical studies to evaluate the long-term safety and efficacy of these new devices, including the risks associated with prolonged insertion and how long the filter could be left in without putting the patient at risk." *Id.* ¶ 597. But Bard "failed to provide patients and doctors with information about appropriate laboratory test(s) and evaluations that could protect against adverse events," despite risks it knew were associated with the Recovery and G2 filters. *Id.* ¶¶ 598-99.

Dr. Kessler's second report provides additional opinions on the Eclipse filter, and assesses a host of misleading statements from Bard relating to off-label use of its filters. As with the Recovery and G2 filters, Dr. Kessler concludes that Bard made misleading statements concerning the Eclipse, implying that migration risks were a class effect, rather than a particular concern to the Eclipse. Supp. Rep. ¶ 10. Dr. Kessler also provides a detailed review of FDA regulations concerning off-label promotion, and concludes that Bard had engaged in promotion of its filters for non-cleared uses, a marketing strategy that increased the number of patients at risk for the adverse events associated with Bard's filters. *See id.* § II(C); ¶¶ 96-106.

IV. APPLICABLE LEGAL STANDARD

Bard's motion does not state, let alone apply, the standard governing admission of expert testimony. As this Court has explained, "Expert testimony is admissible if it will 'assist the trier of fact to understand the evidence or to determine a fact in issue,' if the witness is 'qualified as an expert by knowledge, skill, experience, training, or education,' and if the proposed testimony is sufficiently reliable." *FreeLife Int'l, Inc. v. Am. Educ. Music Publications Inc.*, No. CV07-2210-PHX-DGC, 2010 WL 1252568, at *1 (D. Ariz. Mar. 25, 2010) (quoting Fed. R. Evid. 702 and citing *Daubert*, 509 U.S. at 590). Expert testimony is sufficiently reliable "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702.

The trial court serves as a "gatekeeper for expert testimony to assure that it is both relevant and reliable." *Avila v. Willits Envtl. Remediation Trust*, 633 F.3d 828, 836 (9th Cir. 2011) (citing *Daubert*, 509 U.S. at 592-93). This Court has emphasized, "In serving its gatekeeping function, the court must be careful not to cross over into the role of fact-finder. It is not the job of the court to insure that the evidence heard by the jury is error-free, but to insure that it is not wholly unreliable." *Long v. TRW Vehicle Safety Sys. Inc.*, No. 09-cv-2209, 2011 WL 5007431, at *3 (D. Ariz. Oct. 20, 2011) (quotation and citation omitted). This Court has also noted that "the 2000 amendments to Rule 702 'were not intended to signal an abandonment of the liberal attitude of the Federal Rules of Evidence toward the admissibility of opinion testimony.'" *Wichansky v. Zowine*, No. CV-13-1208-PHX, 2016 WL 6818945, at *3 (D. Ariz. Mar. 22, 2016) (quoting 4 J. Weinstein & M. Berger, Weinstein's Federal Evidence § 702.05[2][a] (2d. ed. 2015)).

V. ARGUMENT

Dr. Kessler's testimony will assist the trier of fact to understand facts in issue, including Bard's failure to follow the standard of care for a medical device manufacturer in bringing its filters to market, and in navigating the regulatory processes that applied to the filters. As this Court has held, "The FDA regulatory process is complex and beyond the experience of the average juror." *Placencia v. I-Flow Corp.*, No. CV10-2520 PHX DGC, 2012 WL 5877624, at *10 (D. Ariz. Nov. 20, 2012). Dr. Kessler is unquestionably qualified by "knowledge, skill, experience, training, or education" to offer his opinions, and his testimony, based upon that experience and a methodical review of vast amounts of information, has a sound factual basis and is reliable. Fed. R. Civ. P. 702.

A. Dr. Kessler's Testimony Will Assist the Jury and Will Not Include Legal Conclusions.

Dr. Kessler's reports and testimony make clear that he intends to offer opinions concerning regulatory issues, including Bard's interactions with and representations to the FDA concerning its filters. Testimony about what Bard did to gain clearance for the filters at issue, as well as what it should have done, are relevant to the determination of

whether Bard acted as a reasonably prudent manufacturer. That testimony will aid the fact-finder, and comes nowhere near instructing it on the law.

Numerous courts, in admitting Dr. Kessler's testimony, have concluded, as this Court did in *Placencia*, that FDA procedures are complex, and as such, a proper subject of expert testimony. For example, in the *In re Testosterone Replacement Therapy* litigation, the court held, "The field of FDA regulation of pharmaceutical products and marketing is highly complex, and a jury reasonably requires assistance to understand it." *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 1836443, at *15 (N.D. Ill. May 8, 2017)[4] (citing *In re Yasmin*, No. 3:09-MD-2100-DRH, 2011 WL 6302287, at *12 (S.D. Ill. Dec. 16, 2011) ("[T]he Court finds that Dr. Kessler's testimony is permissible because of the complex nature of the process and procedures and the jury needs assistance understanding it.")). *See also In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009) (holding that "[a] lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical industry," and that the regulatory expert's "assessment of the reasonableness of Merck's conduct in light of her experience and her understanding of FDA regulations will be helpful to the jury").

It appears that Bard's real objection to Dr. Kessler's testimony is not that he is offering legal conclusions or will instruct the jury (he is not and will not), but that Dr. Kessler, as a former regulator, physician, and undisputed expert on food and drug regulation, somehow cannot be cross-examined persuasively. The defendant in the *Testosterone* litigation made a similar argument as to Dr. Kessler, which the Court rejected. "Specifically, [defendant] suggests that based on his background, plaintiffs will be able to portray him as the ultimate authority in his field. The Court is somewhat perplexed by this objection; [the defendant] seems to be arguing that Dr. Kessler is *too*

[4] The *Testosterone* court held that Dr. Kessler's testimony, concerning off-label marketing and FDA regulations, "is neither irrelevant, otherwise improper, or unfairly prejudicial or confusing." *Id.*

qualified to testify." *In re Testosterone*, 2017 WL 1836443, at *15. Bard's argument that Dr. Kessler, as a former FDA commissioner, who has taught on food and drug law and testified before Congress on relevant issues, "will trade on this experience," echoes this rejected argument. Bard's argument that Dr. Kessler's extensive and relevant experience is somehow a reason to preclude his testimony finds no support in the case law or the plain text of Rule 702.[5]

Further, as an experienced witness, Dr. Kessler is clearly aware of the difference between the Court's role and his role as an expert; he repeatedly states, as Bard concedes, that he is not offering legal opinions, but is instead focused on industry and regulatory standards. *See* Mem. at 6-7 (citing deposition testimony in which Dr. Kessler disclaims any intention of offering legal opinions). In the face of this unambiguous testimony, Bard attempts to spin Dr. Kessler's plainly stated awareness of those lines into an intention to blur them. Bard argues, "Through his expert witness experience, Dr. Kessler has learned to make some of his legal conclusions regarding regulatory compliance more subtle than others." Mem. at 7. But Bard provides no basis for that accusation. Dr. Kessler's testimony demonstrates that he is aware of the lines that the courts apply, and to which experts must adhere; this Court is the ultimate authority on establishing the limits on expert testimony at trial, and such limits will apply equally to all experts.

B. Bard Mischaracterizes Dr. Kessler's Opinions as "Narrative."

As this Court is aware, this litigation involves multiple iterations of a medical device, the first of which went to market nearly fifteen years ago. Plaintiffs' master complaint asserts more than a dozen causes of action, including violations of numerous states' consumer fraud and unfair trade practices statutes. *See* ECF 364. Dr. Kessler has reviewed a vast amount of material, applied his expertise, and assessed the reasonableness

[5] In a similar vein, Bard twice accuses Dr. Kessler of offering his opinions with the "false imprimatur of the FDA itself." Mem. at 3, 7. Bard's accusation makes no sense, even when repeated. Dr. Kessler provides his opinions not as a current FDA official, and Bard points to nothing in his reports that supports its casual accusation that he is somehow misrepresenting his opinions as having the "imprimatur" of the FDA.

of Bard's conduct in lengthy and detailed reports, which provide a clear roadmap of the testimony he will give at trial.

Bard's response is that the reports are too long. It argues that Dr. Kessler intends to present a factual narrative that should come from percipient witnesses, rather than opinions. Mem. at 7-9. Courts have repeatedly rejected precisely this argument, which both mischaracterizes Dr. Kessler's opinions and misapplies the rules governing expert opinion. Consistent with Fed. R. Civ. P. 26 and Fed. R. Evid. 702, both of which require an account of the factual basis for expert opinions, Dr. Kessler's detailed Reports set forth his opinions based on the evidence of Bard's conduct over a period of years.

Dr. Kessler's factual summaries are accompanied by, and provide the necessary basis for, his regulatory opinions. For example, Dr. Kessler's first report provides a comprehensive summary of the regulations and standards applicable to Bard's conduct, including the obligation under Section 510(k) to show equivalent safety and effectiveness to a specific predicate device (Rep. ¶¶ 20-54), then methodically catalogues the evidence supporting his opinions that Bard did not comply with those standards. Paragraphs 144-181 summarize Bard's ever-increasing evidence of risks of the Recovery filter, including the risk of death; paragraphs 182-190 then provide the regulatory opinions that Bard did not meet the applicable standard because the Recovery filter was not as safe as its predicate or other filters. Dr. Kessler's Report then provides an analogous presentation as to the G2 filter (¶¶ 340-465), where relevant facts are accompanied by regulatory/standard of care opinions based on those facts, at ¶¶ 355, 385, 426, 427, 438, 461, 464, and 465.

Dr. Kessler's second report follows the same structure. Dr. Kessler first describes the regulatory framework in which Bard operated, Supp. Rep. ¶¶ 11-31, and then updates his initial report to detail the factual basis for his conclusion that Bard's representations concerning the Eclipse filter were misleading, and his conclusion that Bard had engaged in misleading promotion of its filters, including improper promotion for non-cleared, off-label uses. Bard mistakes the factual basis set forth in Dr. Kessler's reports, which

Federal Rule of Civil Procedure 26 and Federal Rule of Evidence 702 require, for a preview of his "opinions" on the stand.[6]

Dr. Kessler's careful review of the record will be helpful to the jury. The record of Bard's failure to act as a reasonable medical device manufacturer spans many years, and has left a voluminous record; in providing the basis for his regulatory opinions, as he is required to do, Dr. Kessler's reports reflect that lengthy record. That necessary length and level of detail to address that record provide no basis to exclude his opinions. One court held that this argument, also directed at Dr. Kessler, amounted to a complaint that his report contained "too much information," an argument the Court held "borders on specious and is wholly without merit." *In re Actos*, 2014 WL 120973, at *14 ("Dr. Kessler will be asked questions by Plaintiffs' counsel and Dr. Kessler will answer, whether those questions might or might not call for a narrative answer, remains to be seen and Dr. Kessler's report is not objectionable because of the amount of information it contains.").

In another case, a defendant argued, as Bard does here, that "Dr. Kessler's testimony is improper because he 'simply regurgitate[s] evidence that could be presented directly to the jury.'" *In re Testosterone*, 2017 WL 1836443, at *15. The Court rejected that argument, holding that "to the extent he is summarizing voluminous records and materials, as appears to be the case, this aspect of his testimony is properly admitted under Federal Rule of Evidence 1006 as well as Rule 702 in the sense that he is identifying what he, given his background and expertise, considers to be the most salient aspects of those voluminous materials." *Id.* *See also Wells v. Allergan*, 2013 WL 7208221, at *2 ("To the extent the facts relied upon by Dr. Kessler are relevant and not cumulative, Dr. Kessler may include them in his testimony.… Defendant may object at trial if Dr. Kessler appears

[6] Bard does not challenge the opinions in Dr. Kessler's Second Supplemental Report on this (or any other specific) basis.

to be simply regurgitating facts, rather than using relevant facts as context for his expert opinions.").[7]

Far from offering a mere narrative, Dr. Kessler is well qualified to assist the jury in understanding complex and technical regulatory processes and issues. Contrary to what Bard's argument implies, most of the documents do not simply speak for themselves. An expert, like Dr. Kessler, can assist the jury in understanding documents where "the inferences those documents may or may not support are not at all simple." *In re Welding Fume Prod.*, No. 1:03-cv-17000, 2005 WL 1868046, at *17 (N.D. Ohio Aug. 8, 2005). An expert has a clear role to play to "allow the trier of fact to better understand what the documents do (and don't) mean, and, thus, what the defendants did (or didn't) know." *Id.*[8]

C. Dr. Kessler's Opinions on Information Withheld from the FDA Are Relevant and Not Preempted.

Bard argues that Dr. Kessler should not be permitted to opine on the question of whether Bard's filters "would not have been cleared" had Bard disclosed (in other words,

[7] Bard ignores each of these cases, which involve Dr. Kessler himself, and relies on inapposite authority (Mem. at 8). For example, in *In re FEMA Trailer Formaldehyde Prods. Liab. Litig.*, No. MDL 07-1873, 2009 WL 2169224, at *3 (E.D. La. July 15, 2009), the Court excluded the opinions of a so-called "human factors" expert who had relied on her consideration of other experts' reports and of the warnings at issue. The Court held that the jury should hear testimony "from actual experts who have specialized, technical knowledge on the subject matter of this litigation," as Dr. Kessler does. In *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323 (S.D. Fla. 2010), the Court excluded the opinions of the plaintiffs' regulatory expert because she made "no effort to confine it to her area of expertise: the FDA regulatory scheme." *Id.* at 1345. Here, Dr. Kessler's opinions are confined to his area of expertise. In *Lopez v. I-Flow Inc.*, No. CV 08-1063, 2011 WL 1897548, at *10 (D. Ariz. Jan. 26, 2011), the Court found that the expert's report was difficult to follow, as it provided little explanation or analysis of the documents and regulations cited. Here, Bard complains that Dr. Kessler has provided *too much* explanation and interpretation.

[8] Bard's statement (Mem. at 7 n.1) that Dr. Kessler's reports are "based" on the schedules appended to his report is simply wrong, as even a cursory review of those schedules would reveal. The schedules, which reflect Rule 26(b)(2)(B)'s requirement that an expert identify the facts or data considered in forming his opinions, include 29 sets of factual information, such as the names of plaintiffs and clinical studies relating to Bard filters. Bard does not, and cannot, explain how Dr. Kessler's reports simply track, or are otherwise "based" on those information sources.

not withheld) certain information from the FDA. Mem. at 9. Bard's argument again mischaracterizes Dr. Kessler's testimony, and again ignores numerous judicial decisions rejecting the same argument, including specifically pertaining to Dr. Kessler. Contrary to Bard's assertions, Dr. Kessler's opinions on what Bard told the FDA or withheld from the FDA are neither speculation nor conjecture. Instead, the opinions that Bard specifically complains about are based on his review of Bard's own words and actions in trying to market its filters, applying the concept of "substantial equivalence," a regulatory concept about which Dr. Kessler is plainly qualified to opine and that is directly relevant to this litigation.

Bard block quotes three paragraphs of Dr. Kessler's report in its brief (at page 9) that it asserts are speculation about the FDA's actions. Mem. at 9. Those opinions follow Dr. Kessler's review of numerous internal documents from Bard that showed that Bard was aware that certain ("short leg span") Recovery filters did not pass migration resisting testing unless the hooks were engaged. *See* Rep. ¶¶ 85-98.[9] Even as it sought to demonstrate to the FDA "substantial equivalence" between the Recovery and its predicate device, the SNF, Bard did not disclose to the FDA the problems it had encountered with the "short leg span filters." Dr. Kessler opined that these failures raised safety and effectiveness concerns that preclude a finding of substantial equivalence to the predicate device, as required by the 510(k) regulations, and that Bard had an obligation to disclose such failures. These opinions are squarely within Dr. Kessler's expertise, and relevant to the issues in this litigation.[10]

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[9] Bard's failure to disclose problems concerning migration resistance testing was only one of several misrepresentations that Bard made in testing the safety and efficacy of its filters prior to release and which Dr. Kessler details in his report. *See, e.g.*, Rep. ¶¶ 103-122 (describing animal study in which Bard misrepresented to the FDA the maximum pressure achieved).

[10] The two other opinions that Bard highlights in this section of its motion (Mem. at 9-10) also concern Dr. Kessler's application of the substantial equivalence standard. The third is a purely factual statement that the Denali trial had been completed when Bard received clearance for the Denali filter, and it is difficult to understand how it relates to Bard's argument.

Courts have repeatedly rejected attempts to preclude similar testimony. In fact, Bard fails to cite a recent case in which the Court ruled against it on this very issue, as to Dr. Kessler. In *In re C.R. Bard, Inc., Pelvic Repair System Products Liability Litigation*, 948 F. Supp. 2d 589 (S.D. W. Va. 2013), the Court held that Dr. Kessler was permitted to testify, in a failure-to-warn case, that defendant Bard "did not disclose certain information to the FDA that Dr. Kessler, a former Commissioner of the FDA, would have found pertinent." *Id*. at 630.

Similarly, in the *Yaz* case, the district court held:

> As the former Commissioner of the FDA, with unquestioned knowledge of the regulatory scheme and requirements, Dr. Kessler may testify about what a reasonable FDA official would have done with information about VTE [venous thromboembolic] adverse events because *his experience uniquely qualifies for him to do so.* His testimony with regard to these matters is relevant and reliable and can be subject to cross-examination.

2011 WL 6302287, at *13 (emphasis added). In the *Diet Drugs* case, the district court allowed the plaintiffs' expert to testify as to "what reasonable FDA officials . . . would do with adverse event information." *In re Diet Drugs Prod. Liab. Litig.*, No. MDL 1203, 2001 WL 454586, at *19 (E.D. Pa. Feb. 1, 2001). The court held that "to the extent that [plaintiffs' expert/FDA official] opines about how information should be communicated to the FDA and what information should be reflected in labels, as mandated by applicable regulations, he is undoubtedly qualified to do so in light of his experience as an FDA officer." *Id.* at *18. The Court also denied the defendant's motion to exclude the expert's testimony about the standard of care in the pharmaceutical industry regarding the *manner in which certain information should be communicated to the FDA*; and (b) *what FDA officials would have done with certain additional information such as particular adverse event reports.*" *Id*. at *24 (emphasis added).

For the same reasons, Dr. Kessler is well-qualified to offer relevant and reliable testimony as to what a reasonable FDA official would have done with information about

Bard's analyses of adverse events and failure of its filters to meet engineering standards, had Bard disclosed that information.

Finally, with no analysis, Bard argues that Dr. Kessler's opinions concerning FDA actions and regulatory compliance are preempted. Mem. at 10-11. Bard's argument appears to be based on the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), which held that state fraud-on-the-FDA claims are preempted by federal law. Courts in numerous products liability cases since *Buckman* have had no difficulty recognizing that *Buckman* is not applicable to cases, like this one, in which plaintiffs have made no claim for fraud on the FDA. For example, in the *Yaz* litigation, Judge Herndon, noting the plain distinction from *Buckman*, which involved claim preemption, and a failure to warn case that did not assert a "fraud on the FDA" claim, held that "there is no way to analyze *Buckman* to have any impact on this case." *In re Yasmin*, 2011 WL 6302287, at *11. Judge Herndon held that the Supreme Court, in *Wyeth v. Levine*, 555 U.S. 555 (2009), "made clear … that federal law does not prevent judges and juries in failure to warn cases from considering a drug companies [sic] compliance with FDA regulations." *Id.*

Similarly, in the *Vioxx* litigation (in which Dr. Kessler testified), Judge Fallon also denied *Buckman*-based defense motions. After a *Daubert* hearing, Judge Fallon held that *Buckman*'s holding was limited to fraud-on-the-market cases, which rendered it "completely inapplicable to the issue at hand." *In re Vioxx Prods. Liab. Litig.*, 401 F. Supp. 2d 565, 587 (E.D. La. 2005). The Court reiterated: "*Buckman* is not applicable to this case or issue at all," noting that the expert's testimony would "help the jury understand the applicable FDA regulations and [the defendant's] responses." *Id.* at 595.[11] The same conclusion is appropriate here.

[11] Bard's citations (Mem. at 9) to *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029 (D. Minn. 2007), and *Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802 (N.D. Ohio 2002), are inapposite. In *Baycol*, the Court, citing to *Bouchard*, emphasized that "evidence offered *only* to show that the FDA was misled or that evidence was intentionally concealed from the FDA would be excluded." 532 F. Supp. 2d at 1053 (emphasis in original). However, the Court did not preclude the same evidence if it was

D. Dr. Kessler May Offer Opinions Concerning Bard's Representations to the FDA.

Bard identifies three paragraphs from Dr. Kessler's reports that it characterizes as opinions concerning design, testing, and causation, and contends that they are outside of Dr. Kessler's area of expertise. Mem. at 11-12. Bard's characterization of those opinions is incorrect.

Dr. Kessler is not offering opinions concerning, for example, whether Bard's filters were defectively designed. He can, however, opine on whether Bard provided incomplete or misleading information to the FDA as it sought clearance for a device that it contended was substantially equivalent to its predicate device. All of the opinions that Bard identifies as outside of Dr. Kessler's expertise are included in his reports after a thorough review of Bard's actions as they related to its claims of substantial equivalence.

For example, Bard suggests that Dr. Kessler's conclusion that Bard should not have referenced a maximum venous pressure in creating performance specifications is a "design" opinion. Mem. at 11. This opinion, however, is part of Dr. Kessler's conclusion that Bard based its claims of substantial equivalence on "flawed performance specifications." Rep. ¶ 137. That opinion, and Dr. Kessler's conclusion that Bard's off-label promotion was misleading because it "failed to warn about the increased risk of movement/migration of its filters compared to permanent only filters," are squarely within Dr. Kessler's expertise, as they concern regulatory non-compliance, a subject that courts have found to be relevant in failure-to-warn cases. *See, e.g., In re Yasmin*, 2011 WL 6302287, at *11; *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 900 (D. Minn. 2006) (holding that "plaintiffs may use evidence… of Medtronic's efforts to manipulate the regulatory process in order to prove their negligence and strict liability claims").

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offered to show that the medical community, patients, or treating physicians were also misled.

E. Dr. Kessler Is Not Opining on Bard's Corporate Ethics or Intent.

Bard concludes its brief by asserting that Dr. Kessler should not be permitted to offer opinions concerning "corporate intent and ethics." Mem. at 12. It is unclear what opinions Bard believes Dr. Kessler intends to offer on these subjects. Bard cites to a handful of Dr. Kessler's statements from his reports and deposition testimony that are purely factual and based on documentary evidence that he reviewed. *See id.* at 13 (referring to early reports of migrations of the G2 filters and Bard's failure to add anchors to the Eclipse filter). Among Bard's list of quotations from Dr. Kessler is one in which he expressly disclaimed any intention to discuss ethics. *Id.* None of the examples that Bard provides remotely touch on intent, motive, or even arguably concern Dr. Kessler's "[p]ersonal views on corporate ethics and morality." *Id.* at 12.

Bard misleadingly cites another filter case, *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307 (M.D. Fla. 2015), for the proposition that the Court excluded "similar opinions." *See* Mem. at 12. Even setting aside that it is not clear which of Dr. Kessler's opinions Bard believes are similar to those at issue in *Tillman*, the *Tillman* decision explicitly *permitted* plaintiff's engineering experts to testify that Bard's conduct was "incompetent" and "misleading." It relied on a Sixth Circuit Court of Appeals decision that expert testimony violates the prohibition against asserting "legal conclusions" where the expert's terminology has "separate, distinct and specialized meaning in the law different from that present in the vernacular." *Id.* at 1325. Thus, the court excluded testimony that a defendant was reckless or negligent (because of the special legal meaning of those terms), and testimony that their conduct was unethical (because it was subjective). *See id.* at 1325-27. However, plaintiff's experts were permitted to offer opinion testimony that Bard's claims were "misleading":

> [T]he Engineers also opine that it is *misleading* for Bard to claim that G2 filters are twelve times more fatigue resistant than Recovery filters, and upon consideration, the Court finds this opinion to be permissible. [Citation omitted]. The Engineers reviewed the testing done to support Bard's claim and determined that the claim is misleading based on their analysis of what the testing actually showed. *An opinion that Bard's claim was*

> *misleading because it was not supported by the tests performed does not relate to legal standards, nor is it a question of Bard's state of mind or intent.*

Id. at 1327 (emphasis added).

In this case, Dr. Kessler does not propose to offer opinions as to whether Bard's conduct was "unethical," nor does he use any other arguably impermissible, specialized legal terms that differ from the vernacular. In contrast, Dr. Kessler offers several opinions that Bard's conduct was "misleading,"[12] a non-specialized term permitted under pertinent case law.

VI. CONCLUSION

For the foregoing reasons, Bard's motion should be denied.

Respectfully submitted this 27th day of September 2017.

GALLAGHER & KENNEDY, P.A.

By:*/s/ Mark S. O'Connor*
Mark S. O'Connor
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Co-Lead/Liaison Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of September, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti

[12] *See, e.g.*, Rep. §§ VIII, IX and X, and accompanying text, at pages 190-207; Supp. Rep. ¶¶ 99, 100, 108.